IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA

MOLLY GUINAN	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 08-0228
A.I. DUPONT HOSPITAL FOR CHILDREN, et al.	:	

SURRICK, J. **FEBRUARY 6, 2009**

MEMORANDUM & ORDER

Presently before the Court are the Motion of Defendant William I. Norwood, M.D., Ph.D., for Summary Judgment Pursuant to Rule 56 of the Federal Rules of Civil Procedure (Doc. No. 20), the Motion for Partial Summary Judgment to Dismiss the First Cause of Action (Doc. No. 21), the Motion for Partial Summary Judgment to Dismiss Count II of the Complaint Alleging Fraud and Intentional Misrepresentation and Punitive Damages Claim (Doc. No. 22), the Joint Motion of Defendants for Summary Judgment or Alternatively for Partial Summary Judgment on Medical Monitoring Claim Set Forth in Count VI (Doc. No. 23), and the Institutional Defendants' Motion for Partial Summary Judgment (Doc. No. 24). For the following reasons, Defendants' Motions will be granted in part and denied in part.

I. BACKGROUND

Plaintiff is one of several infants who had a controversial procedure to correct a congenital heart defect performed on her by doctors at the A.I. duPont Hospital for Children in

Wilmington, Delaware.[1] Plaintiff was born with Down Syndrome and a combination of three heart defects: tetralogy of Fallot, complete common atrioventricular canal defect, and severe pulmonary stenosis.[2] These defects are uncommon but well-known congenital cardiac malformations that accompany Down Syndrome. The defects' primary effect on Plaintiff was to prevent her right ventricle from performing its function of receiving deoxygenated blood from the right atrium and pumping that blood to the pulmonary artery for oxygenation in the lungs. This, in turn, resulted in Plaintiff having insufficiently oxygenated blood, giving Plaintiff's skin a bluish or purple color.

Defendant Dr. Norwood decided that a shunting procedure known as the Fontan procedure was the most appropriate treatment for Plaintiff's condition. (Doc. No. 33, Ex. YY at 38 (hereinafter, "Norwood Dep."); (Doc. No. 20, Ex. A ¶¶ 2, 4 (hereinafter, "Norwood Decl.").) In Plaintiff's case, the Fontan procedure modified the physiology of her heart to "allow blood to bypass [her] non-functioning right ventricle and go directly and passively to the lungs to be oxygenated." (Norwood Decl. ¶ 5.) When Plaintiff was born on March 12, 2001, achieving the so-called Fontan physiology required two open heart surgeries, the Hemi-Fontan and the Fontan

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[1] For purposes of this opinion, we refer to Molly Guinan as "Plaintiff"; A.I. duPont Hospital for Children, the Nemours Foundation, the Nemours Cardiac Center, and the Nemours Delaware Institutional Review Board as the "Institutional Defendants"; and Doctors William Norwood and John Murphy as the "Medical Defendants." Plaintiffs voluntarily dismissed Defendant Doctor Kenneth Murdison in December, 2004. (*See* No. 04-cv-4862, E.D. Pa., Doc. No. 18.)

[2] The nature of this case requires frequent use of medical vocabulary. We will define terms that are necessary to the legal outcome of this case. Definitions of other medical terms used in this opinion can be found in any one of several readily accessible sources, such as *Stedman's Medical Dictionary* (28th ed. 2006) or Medline Plus, http://www.nlm.nih.gov/medlineplus/mplusdictionary.html.

completion ("Surgical Completion"), respectively. (*See* Norwood Decl. ¶¶ 6-10.) Dr. Norwood performed a Hemi-Fontan on Plaintiff two months after she was born, on May 14, 2001. (*Id.* ¶ 4.) The sequence of events that precipitated the instant lawsuit began with the second surgery.

Plaintiff was scheduled to have a Surgical Completion of her Fontan on May 9, 2002. However, instead of having her Fontan completed, Plaintiff had her atrioventricular valves repaired. There is disagreement with regard to the goal of the second surgery. On one hand, Plaintiff's parents thought that Dr. Norwood was going to perform the Surgical Fontan, and it was not until after the surgery was over that Plaintiff's parents discovered that the Fontan had not been completed. (*See* Doc. No. 33, Ex. L Vol. I at 101 (hereinafter, K. Guinan Dep. Vol. I").) On the other hand, Dr. Norwood indicates that, prior to the surgery, it was apparent that Plaintiff had developed "severe leakage of her atrioventricular valves, [which] obviat[ed] for the moment the second stage of her Fontan procedure." (*Id.* ¶ 12; *see also* Norwood Dep. at 47 (noting that completing the Fontan and repairing Plaintiff's atrioventricular valve at the same time was not "the most favorable way of dealing with [Plaintiff's] physiology"); Doc. No. 33, Ex. F at 3 (consent form signed by Plaintiff's father describing surgical procedure as "repair mitral valve").) In any event, the May 9, 2002, surgery did not result in Plaintiff receiving a Fontan completion.

After the surgery, Plaintiff's attending physician, cardiologist Dr. Samuel Gidding, informed Plaintiff's parents that the Fontan had not been completed but that the procedure could be completed in the catheter lab. (*Id.* at 101.) Completing the Fontan in the catheter lab involved a relatively new procedure that entailed a cardiologist employing a covered stent via

catheter to complete the Fontan procedure intravascularly ("Catheterization Fontan").[3] (*See* Norwood Decl. ¶ 9; *see also, e.g.*, Doc. No. 33, Ex. DDD at 72 (hereinafter, "Mullins Dep.") (describing some benefits of catheterization over open heart surgery).) The theoretical advantage of such a procedure was that it avoided the risks that accompany open-heart surgery. The parties present very different versions of what occurred from this point forward in Plaintiff's treatment. However, the following facts are not in dispute.

On October 14, 2002, cardiologist Dr. Murphy implanted a Cheatham Platinum covered stent ("CP stent") in Plaintiff. The CP stent was manufactured by NuMed, Inc., a New York corporation that is one of the few developers of pediatric medical devices in the United States. (*See* Mullins Dep. at 34-38.) The CP stent had not been approved by the Food and Drug Administration when Dr. Murphy implanted the CP stent in Plaintiff. On the day Plaintiff had the procedure performed, Plaintiff's father signed a consent form provided by the Hospital that described the procedure as "Transcatheter placement of intravascular stent: Covered stent completion of cavopulmonary connection." (Doc. No. 25, Ex. 5 at 2 (hereinafter, "duPont Consent Form"); (Doc. No. 33, Ex. K at 283 (hereinafter, "J. Guinan Dep.").)

About a month after the procedure, Plaintiff developed symptoms of a cold. (J. Guinan Dep. at 85.) Plaintiff's mother contacted Dr. Gidding about the symptoms and he advised that

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[3] It is not clear when or how Dr. Murphy and Dr. Norwood developed the concept of achieving a Fontan physiology by using a catheter and CP stent. They were not, however, the first to use the procedure. Dr. John Cheatham, the CP stent's creator, used the stent for a Fontan completion on at least one occasion over a year before Dr. Murphy implanted the stent in Plaintiff. (Doc. No. 33, Ex. G at 86, 105 (hereinafter, "Cheatham Dep.").) Dr. Gerd Hausdorf, a physician in Germany, developed and implemented the idea before Dr. Cheatham. (*See, e.g.*, *id.* at 106.) In fact, it appears that doctors have conceived of several uses for the CP stent, including treatment for pulmonary artery stenosis, coarctation of the aorta, single balloon catheter and transcatheter Fontan completion, and right ventricle outflow tract obstruction. (*Id.* at 136.)

she and Plaintiff's father monitor Plaintiff's blood oxygen saturation. (*Id.* at 86-87.) Plaintiff's symptoms gradually became worse, requiring several trips to the hospital. (*See generally id.* at 90-121.) Plaintiff was eventually diagnosed with protein losing enteropathy ("PLE") and plastic bronchitis, both rare and potentially life-threatening conditions.

Dissatisfied with the responsiveness and general conduct of the doctors in the Nemours Cardiac Center, Plaintiff's parents started bringing her to the Pediatric Intensive Care Unit at the A.I. duPont Hospital, which is separate from the Nemours Cardiac Center. (*See id.* at 140-41.) In May 2003, Plaintiff's parents decided to transfer Plaintiff to the care of Dr. Jack Rychik, Dr. Thomas Spray, and Dr. Jonathan Rome at the Children's Hospital of Philadelphia ("CHOP"). (*Id.* at 150-52.) Plaintiff's PLE eventually dissipated, but her plastic bronchitis remained. (*See id.* at 169.)

Dr. Rychik determined that he would not remove the CP stent. Rather, he determined that the best course of treatment for Plaintiff's plastic bronchitis was to leave the CP stent in and fenestrate, or create a hole in, it. (*See* Doc. No. 25, Ex. 21 at 22 (hereinafter, "Rome Dep.") ("[T]he decision to fenestrate was based on the fact that we didn't identify other specific things to fix, if you will."); K. Guinan Dep. Vol. I at 186-87; J. Guinan Dep. at 160.) Fenestration is a known, although not widely agreed upon, procedure intended to lower pressure in the venous system and thereby alleviate PLE and plastic bronchitis, which sometimes accompany the increased venous pressure associated with Fontan physiology. (*See* Norwood Dep. at 64-66, 78-79; *see also* Cheatham Dep. at 64-65; Doc. No. 25, Ex. 22 at 54 (hereinafter, "Jacobs Dep.") ("[S]ome centers feel that fenestration is useful and they try to do it. Other centers feel that it's never useful.").) Although Dr. Rychik and Dr. Rome had limited experience dealing with the

CP stent and general experience performing fenestrations and working with Gore-Tex, they came to the conclusion that the Gore-Tex material that covered the stent might close back up if it were fenestrated. (Rome Dep. at 33-35; J. Guinan Dep. at 164, 292.) They conveyed this concern to Plaintiff's parents, who elected to proceed with the fenestration with that knowledge. (J. Guinan Dep. at 164; Doc. No. 33, Ex. L Vol. II at 108 (hereinafter, "K. Guinan Dep. Vol. II").) Prior to the procedure, Dr. Rychik and Dr. Rome determined that Plaintiff's pulmonary artery was narrowing and needed a stent to hold it open. (Rome Dep. at 23.) Plaintiff's parents consented to having a second (non-CP) stent placed in the artery to address the narrowing. (J. Guinan Dep. at 158; K. Guinan Dep. Vol. I at 190-91.)

On December 17, 2004, Dr. Rychik used a catheter to fenestrate the CP stent and to implant a stent in Plaintiff's pulmonary artery. (J. Guinan Dep. at 169.) In February, 2006, Dr. Rychik and Dr. Rome discovered that the fenestration in Plaintiff's CP stent was only allowing a "relatively small amount of blood" to pass through it. (Rome Dep. at 24.) Dr. Rychik suggested enlarging the fenestration in a procedure that would result in an extremely small stent sitting in the fenestration at a right angle to the CP stent. (*Id.* at 25.) Stents are sometimes used in the same way when cardiologists fenestrate surgically-completed Fontan physiology. (*See id.* at 34-35.) Plaintiff's parents agreed, and Dr. Rychik performed the procedure. (*See* K. Guinan Dep. Vol. II at 116-20; J. Guinan Dep. at 292-94.)

Plaintiff currently has three stents in her body. (J. Guinan Dep. at 287-88.) She has the CP stent, which completes her Fontan physiology; a non-CP stent that prevents her pulmonary artery from narrowing; and a non-CP stent holding the fenestration of the CP stent open. (*Id.*) In February 2007, the doctors at CHOP did an echocardiogram that showed that the fenestration

was still open. (*Id.* at 293; Rome Dep. at 28-30.) However, Plaintiff's plastic bronchitis persists. (J. Guinan Dep. at 293; Rome Dep. at 29.) A take-down Fontan procedure remains a last resort for treating Plaintiff's plastic bronchitis. (Doc. No. 33, Ex. SS at 2; J. Guinan Dep. at 294.) Plaintiff's cardiothoracic surgeon at CHOP, Dr. Spray, believes that returning Plaintiff's heart to a Hemi-Fontan physiology might alleviate the pulmonary cast formations associated with plastic bronchitis because Plaintiff did not have that problem in the interim between her Hemi-Fontan procedure and the completion of the Fontan. (*See* Doc. No. 33, Ex. SS at 2.)

While there is little or no dispute over these facts, a number of events and circumstances concerning Plaintiff's medical treatment by the Medical Defendants and the Institutional Defendants are contested.

One factual dispute between the parties concerns whether Plaintiff's parents signed a consent form provided by NuMed or were otherwise informed of the details of the CP stent and the nature of the Catherization Fontan prior to the surgery. (Doc. No. 25, Ex. 4 (hereinafter, "NuMed Consent Form").) The guardians of most, if not all, of the other patients at the Nemours Cardiac Center who had the Catheterization Fontan using the CP stent signed a NuMed Consent Form indicating that the device was investigational and not FDA-approved. Plaintiff's parents contend that they never signed this form. (K. Guinan Dep. Vol. I at 87-88, 113, 117, 228; *see also* J. Guinan Dep. 173, 283-85.) Moreover, they contend that they were not informed in any way by the Medical Defendants that the CP stent was not FDA-approved or that the Catheterization Fontan was an innovative procedure with a limited track record. (*See* K. Guinan Dep. Vol. I at 112-17; J. Guinan Dep. 75-77.)

As mentioned above, factual disputes exist over how Dr. Norwood performed the May 9,

2002, procedure. In addition to the discrepancies between what the parties believed to be the purpose of the surgery, disagreement remains over how Dr. Norwood performed the surgery. Specifically, during the course of the surgery, Dr. Norwood placed a Gore-Tex collar in Plaintiff's inferior vena cava. (Norwood Decl. ¶ 14.) Dr. Norwood contends that the placement of the Gore-Tex collar "markedly simplified the Fontan circuit if it was to be completed surgically and it could potentially be used to provide an anchor within the heart if [Plaintiff's parents elected] nonsurgical Fontan completion . . . . The placement of the collar did not commit to either Completion Fontan approach, rather it simplified both." (*Id.*) As with the dispute over whether Plaintiff's parents viewed, signed, or were informed of the contents of the NuMed Consent Form, the issues surrounding Plaintiff's May 9, 2002 procedure concern the extent to which Medical Defendants informed Plaintiff's parents as to Plaintiff's course of treatment.

Finally, there are factual disputes surrounding the treatment Plaintiff received when her PLE and plastic bronchitis first began manifesting themselves in December 2002 or January 2003. At her deposition, Plaintiff's mother described her dissatisfaction with the Medical Defendants' and Institutional Defendants' treatment of her daughter. (*See* J. Guinan Dep. at 98-145.) That dissatisfaction led Plaintiff's mother to file several formal complaints with A.I. duPont Hospital and its Institutional Review Board. (*See* Doc. No. 33, Ex. JJ at 21 (hereinafter, "March 30, 2004 Letter").) It was these complaints that first made the Institutional Defendants aware of the fact that the Medical Defendants were using the CP stent. This prompted an internal review process within the A.I. duPont Hospital. (*See id.* at 18.)

This lawsuit was originally filed as a class action. Plaintiff was one of the named plaintiffs representing a class of patients who had received Catheterization Fontans with CP

stents at the A.I. duPont Hospital for Children in Wilmington, Delaware. In February 2007, we granted the Medical Defendants' motion to dismiss. Specifically, we dismissed certain theories of negligence under the Plaintiff's first cause of action. We also dismissed Plaintiff's third cause of action for assault and battery, Plaintiff's fourth cause of action for strict products liability, and Plaintiff's fifth cause of action for breach of express and implied warranty. (*See* No. 04-cv-4862, E.D. Pa., Doc. No. 50 (hereinafter, "February 14, 2007 Memorandum and Order").) In April 2007, the parties stipulated that all class action allegations in the Complaint would be dismissed and that the request for class certification would be withdrawn. After a scheduling conference in January 2008, an Order was entered upon request of counsel directing that separate civil action numbers be assigned to each of the named plaintiffs and directing that the cases be tried separately. (*See* Doc. No. 1.)

II. LEGAL STANDARDS

A. Summary Judgment

Summary judgment is appropriate when "the pleadings, the discovery, and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); s*ee also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986); *Fed. Home Loan Mortgage Corp. v. Scottsdale Ins. Co.*, 316 F.3d 431, 443 (3d Cir. 2003). Only facts that might affect the outcome of a case are "material." *Anderson*, 477 U.S. at 248. The moving party bears the burden of identifying the absence of a genuine issue of material fact, which it may satisfy by "showing" the court that there is an absence of evidence supporting the non-moving party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 325 (1986); *UPMC Health Sys. v. Metro. Life Ins. Co.*, 391

F.3d 497, 502 (3d Cir. 2004). All reasonable inferences from the record are drawn in favor of the non-movant. *Knabe v. Boury Corp.*, 114 F.3d 407, 410 n.4 (3d Cir. 1997).

Although the movant has the initial burden of demonstrating the absence of genuine issues of material fact, the non-movant must then establish the existence of each element on which it bears the burden of proof. *See Watson v. Eastman Kodak Co.*, 235 F.3d 851, 857-58 (3d Cir. 2000). Plaintiffs cannot avert summary judgment with speculation or by resting on the allegations in the pleadings, but rather must present competent evidence from which a jury could reasonably find in their favor. *Ridgewood Bd. of Educ. v. N.E. for M.E.*, 172 F.3d 238, 252 (3d Cir. 1999); *see also Fin. Software Sys., Inc., v. Lecocq*, No. 07-3034, 2008 U.S. Dist. LEXIS 41699, at *6 (E.D. Pa. May 27, 2008).

B. Choice of Law

Federal courts sitting in diversity jurisdiction must apply the law of the forum state, including its choice of law principles. *See, e.g.*, *Thabault v. Chait*, 541 F.3d 512, 521 (3d Cir. 2008) (*citing Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938); *Pennsylvania v. Brown*, 373 F.2d 771, 777 (3d Cir. 1967)); *First State Underwriters Agency of New England Reinsurance Corp. v. Travelers Ins. Co.*, 803 F.2d 1308, 1316 (3d Cir. 1986) (*citing Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487 (1941)). Pennsylvania courts use a two-step interest analysis to determine choice of law. *See Griffith v. United Airlines Inc.*, 203 A.2d 796, 806-07 (Pa. 1964); *see also Hanover Ins. Co. v. Ryan*, No. 06-2650, 2007 U.S. Dist. LEXIS 92646, at *9-12 (E.D. Pa. Dec. 17, 2007) (discussing *Griffith*). A court must first examine whether a conflict exists between the laws of the competing states. *Hanover*, 2007 U.S. Dist. LEXIS 92646 at *11. If a conflict exists, then the court must "weigh the interests of each state in the resolution of the

dispute, and determine which state has greater contacts with the dispute." *Id.* at *12.

For several of Plaintiff's claims the choice of Delaware law is potentially outcome determinative. We will therefore conduct the choice of law analysis.[4]

1. Negligence: Medical Negligence and Informed Consent

Plaintiff articulates two different theories of negligence: (1) medical negligence premised on malpractice; and (2) lack of informed consent. A conflict exists between the laws of Pennsylvania, Delaware, and New Jersey with regard to both theories of negligence arising from the provision of medical services. We address each in turn.

There are conflicts between the law of Delaware and the laws of Pennsylvania and New Jersey with regard to Plaintiff's medical negligence claims. Pennsylvania and New Jersey both require courts to apply a "substantial factor" test to issues of causation in medical malpractice cases. *See Winschel v. Jain*, 925 A.2d 782, 789 (Pa. Super. Ct. 2007); *Verdicchio v. Ricca*, 843 A.2d 1042, 1058 (N.J. 2004). In contrast, Delaware courts apply a "but for" test to issues of causation in medical malpractice cases. *See Spicer v. Osunkoya*, No. 04-218, 2008 Del. Super. LEXIS 257, at *3 (Del. Super. Ct. 2008). Thus, a conflict exists with regard to Plaintiff's medical negligence claims.

In addition, informed consent in Delaware and New Jersey sounds in negligence. Informed consent in Pennsylvania sounds in battery. *Compare Brzoska v. Olson*, 668 A.2d 1355, 1366 (Del. 1995) ("If a health care provider violates his . . . duty of care in obtaining the consent

[4] Plaintiff has incorrectly assumed that there are no differences between the laws of Pennsylvania, Delaware, and New Jersey with regard to all of the claims except medical monitoring. (*See* Doc. No. 28 at 31-32; Doc. No. 29 at 29-30; Doc. No. 30 at 30-31; Doc. No. 31 at 29-30; Doc. No. 32 at 29-30.)

of the patient by failing to disclose all relevant information (risks) that a reasonable person would deem significant in making a decision to have the procedure, the action should be pleaded in negligence – not battery."), *and Acuna v. Turkish*, 930 A.2d 416, 425 (N.J. 2007) ("The informed consent doctrine has evolved from a concept originally sounding in battery to a firmly established principle of negligence involving the duty of care a doctor owes his patient.") (*citing Howard v. Univ. of Med. & Dentistry of N.J.*, 800 A.2d 73, 77-78 (N.J. 2002), *with Fitzpatrick v. Natter*, 961 A.2d 1229, 1242 n.13 (Pa. 2008) ("An informed consent action . . . sounds in battery rather than in negligence."). Moreover, since informed consent in New Jersey and Delaware is based on negligence, there is a conflict between Delaware and New Jersey law. In Delaware, a plaintiff claiming a lack of informed consent needs to establish that the absence of informed consent was the "but for" cause of his injuries. In New Jersey, the same plaintiff would need to establish that the absence of informed consent was a "substantial factor" in causing his injuries.

Pennsylvania's sole interest with regard to Plaintiff's negligence-based claims is in its role as the forum state. New Jersey's interest is that Plaintiff is its citizen. Delaware, by contrast, has a number of different interests that dictate that Delaware law should apply. Plaintiff intentionally travelled from New Jersey to Delaware to receive treatment. This weighs heavily in favor of applying Delaware law. *See, e.g.*, *Blakesley v. Wolford*, 789 F.2d 236, 243 (3d Cir. 1986) ("[I]t is only fair that the law of the state to which the patient has voluntarily travelled, and in which the doctor has chosen to conduct the operation, be applied to adjudicate the respective rights duties, and obligations between the parties."). The complained-of conduct occurred in Delaware, and Delaware has a strong interest in regulating the activity within its borders. *See Svindland v. A.I. Dupont Hosp. for Children of the Nemours Found.*, No. 05-0417,

2006 U.S. Dist. LEXIS 80601, at *6 (E.D. Pa. Nov. 3, 2006) (looking to where medical treatment occurred as one factor in *Griffith* analysis); *see also* 42 Pa. Cons. Stat. § 5101.1(b) ("[A] medical professional liability action may be brought against a health care provider for a medical professional liability claim only in the county in which the cause of action arose."). Delaware also has an interest maintaining the predictability of its regulations so that health care professionals practicing within its borders know what standards govern their conduct.

2. Fraud and Negligent Misrepresentation

Delaware and New Jersey have significantly curtailed, if not eliminated outright, causes of action for fraud and misrepresentation based on a doctor's failure to inform a patient of risks or concerns associated with medical treatment. *See* 18 Del. C. § 6801(7) (defining medical negligence as "any tort or breach of contract based on health care or professional services rendered, or which should have been rendered, by a health care provider to a patient"); *Howard*, 800 A.2d at 81-82 (disallowing cause of action for fraud where it "would circumvent the requirements for proof of both causation and damages imposed in a traditional informed consent setting"). We are aware of no such rule in Pennsylvania.

As Pennsylvania's only interest is that of the forum state, we can apply the laws of Delaware and New Jersey interchangeably. *See On Air Entm't Corp. v. Nat'l Indem. Co.*, 210 F.3d 146, 149 (3d Cir. 2000) (referring "interchangeably" to the laws of two states in diversity action when there was no conflict between the states' laws). As we discuss above, Delaware has a greater interest in seeing its rules regarding medical negligence and the provision of medical services applied. Accordingly, any difference between the laws in Delaware and New Jersey will be resolved by reliance on Delaware law.

3. Medical Monitoring

Plaintiff acknowledges that a choice of law analysis is necessary for the medical monitoring claim. (*See* Doc. No. 30 at 30-34.) Pennsylvania and New Jersey recognize medical monitoring as a cause of action. However, there are differences between the laws of the two states that create a conflict. *See In re Paoli R.R. Yard PCB Litig.* (*Paoli II*), 35 F.3d 717, 787-88 (3d Cir. 1994) (identifying potential conflict between Pennsylvania and New Jersey medical monitoring causes of action). In Delaware, it is not clear whether medical monitoring is an independent tort or whether medical monitoring is simply a remedy, as it is in many other jurisdictions. *See Brozka*, 668 A.2d at 1359 (explaining procedural history, including lower court's treatment of medical testing and monitoring as a remedy); *Mergenthaler v. Asbestos Corp. of Am.*, 480 A.2d 647, 651 (Del. 1984) (disagreeing with plaintiff's theory that "a claim for the expenses of medically required surveillance and related mental anguish caused thereby is maintainable under Delaware law even if there is no present physical disease" and requiring actual exposure to toxic substance for claim to proceed); *see also Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 572 (6th Cir. 2005) ("[M]edical monitoring is more properly considered one of a number of possible remedies to an underlying tort, rather than a separatately [sic] actionable tort."). Moreover, a definitive choice of law analysis is hindered by Plaintiff's novel theory that a tort claim for medical monitoring can be applied to medical procedures and devices under Pennsylvania, Delaware, and New Jersey law.

With that in mind, it is apparent that Delaware has the greatest interest in seeing its law applied to this action for the same reasons that it has the greatest interest in seeing its medical negligence laws applied. Plaintiff travelled to Delaware to receive medical care. Physicians

licensed by Delaware allegedly committed the tortious conduct, giving Delaware the greatest interest in having its law applied to the facts so that other Delaware-licensed physicians can provide medical services with a clearer view of the law. Moreover, Delaware's law of negligence applies to this action. It imposes burdens on the parties with regard to, among other things, expert testimony and causation. A medical monitoring claim, like any tort, requires Plaintiff to establish causation. *See Paoli II*, 35 F.3d at 787 (listing elements of medical monitoring under Pennsylvania law). Furthermore, because Pennsylvania and Delaware require different proofs with regard to causation, applying Pennsylvania law to Plaintiff's medical monitoring claim and Delaware's law to the negligence claim could conceivably result in an inconsistent outcome.

Plaintiff argues that Pennsylvania has the greatest interest because it is the forum state and because Plaintiff is receiving her current medical care in Pennsylvania at CHOP. (Doc. No. 30 at 34.) Plaintiff does not explain why the location of her current medical care outweighs the interests of Delaware discussed above, or for that matter the interest of New Jersey in the protection of its citizens. Delaware law will control our analysis.

III. LEGAL ANALYSIS

Delaware's Health Care Malpractice Insurance and Litigation Act (the "Health Care Act"), 18 Del. C. §§ 6801 *et seq.*, defines medical negligence as "any tort or breach of contract based on health care or professional services rendered, or which should have been rendered, by a health care provider to a patient." 18 Del. C. § 6801(7). The effect of this all inclusive definition is that the Health Care Act establishes the framework for resolving all legal disputes between healthcare providers and their patients that arise out of the provision of medical

services. A cornerstone of the Health Care Act is the requirement that plaintiffs asserting claims against healthcare providers must support those claims with expert testimony regarding the healthcare provider's deviation from the standard of care and the causal connection between the healthcare provider's deviation and plaintiff's injury. *See* 18 Del. C. § 6853(e) ("No liability shall be based upon asserted negligence unless expert medical testimony is presented as to the alleged deviation from the applicable standard of care in the specific circumstances of the case and as to the causation of the alleged personal injury or death . . . ."). Indeed, the testimony of a competent medical expert is an essential element of any medical negligence claim, including informed consent claims, in Delaware. *See Burkhart v. Davies*, 602 A.2d 56, 59 (Del. 1991), *cert. denied*, 504 U.S. 912 (1992) ("As a result of the [section 6853] statutory mandate, the production of expert medical testimony is an essential element of a plaintiff's medical malpractice case . . . ."); *Patten v. Freedmam*, No. 61, 1989 Del. Super. LEXIS 222, at *7-8 (Del. Super. Ct. May 18, 1989) ("An action based on lack of informed consent is an action for malpractice, and malpractice is defined by a negligence standard. The conclusion follows that an action for malpractice based on lack of informed consent is a negligence action."); *see also* 18 Del. C. § 6854 (setting standard for competency of experts).

The Medical Defendants and the Institutional Defendants argue that summary judgment is appropriate here because Plaintiff has not produced expert testimony regarding causation. (*See* Doc. No. 20 at 17-18; Doc. No. 21 at 25; Doc. No. 23 at 11-12; Doc. No. 24 at 12-14.) Plaintiff responds that the expert testimony she has produced is sufficient to create a genuine issue of material fact. (*See* Doc. No. 28 at 49-51; Doc. No. 30 at 34-42; Doc. No. 31 at 49-50; Doc. No. 32 at 42-50.)

In order to address the question of whether Plaintiff has met her burden as to causation, we must determine the nature of Plaintiff's alleged injury. Viewing the facts in a light most favorable to Plaintiff, it is alleged that Plaintiff suffered three injuries as a result of her treatment: (1) PLE, (2) plastic bronchitis, and (3) an uncertain future.[5] (*See, e.g.*, Doc. No 32 at 42-50.) Delaware law requires Plaintiff to produce expert testimony stating that the Medical Defendant's deviation from the standard of care and the Institutional Defendant's deviation from the standard of care caused each of these injuries. *See* 18 Del. C. § 6853(c).

A. Expert Report

Plaintiff has produced one medical expert, pediatric cardiologist Dr. Paul Grossfeld. (Doc. No. 33, Ex. WW (hereinafter, "Grossfeld Report").) In response to the Defendant's arguments that Plaintiff has not established causation, Plaintiff cites the following paragraphs of Dr. Grossfeld's report:

> As far as [Plaintiff's] future is concerned, given the fact that the CP stent implanted in her on October 14, 2002, was not safe for use in humans[,] that the Cheatham platinum stent has never been shown to be safe or effective for use of stent based Fontan completion, and there was no original plan for long term care and follow up of this implanted device, I find that Molly's future is truly unknown.
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> There is nothing in the deposition of Allen Tower or Dr. Cheatham that would indicate that they have any knowledge as to what the safety and effectiveness of the [CP] stent will be in the future. [Plaintiff] has already had two additional procedures

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[5] At her deposition, Plaintiff's mother raised the issue of whether Plaintiff may have sustained brain damage during her treatment for plastic bronchitis. (*See* J. Guinan Dep. at 138.) Plaintiff's Life Care Planner, Nurse Kathleen Ryan Kuntz, raised the issue as well in her Life Care Plan report for Plaintiff. (Doc. No. 33, Ex. XX at 4, 7.) The only other reference to this isue in the record is from Plaintiff's father, who testified at his deposition that he believes that a computed tomography ("CT") scan was performed on Plaintiff's brain after the event at issue and it was confirmed that Plaintiff had not "suffered irreparable brain injury." (K. Guinan Dep. Vol. I at 180.) Plaintiff does not discuss this potential harm in her briefing and Plaintiff's medical expert does not address it in his report.

> to fenestrate the stent – which was never meant to be fenestrated – in order to deal with her protein losing enteropathy and plastic bronchitis. Clearly, her future is unknown and relies upon the physicians at [CHOP] to continue in their attempts to manage this unknown and unapproved device implanted in [Plaintiff's] heart.

(*See, e.g.*, Doc. No. 28 at 50 (citing Grossfeld Report at 4).) At his deposition, Dr. Grossfeld revised the statement in his report that the CP stent was "not safe for use in humans." (Grossfeld Dep. at 4.) Dr. Grossfeld testified that he should have said that the safety of the stent was unknown. (*See* Doc. No. 25, Ex. 6 at 286-89 (hereinafter, "Grossfeld Dep.").) Dr. Grossfeld further testified that PLE and plastic bronchitis are both known complications of the Fontan physiology that can and do develop even in the absence of negligence by the treating physician. (*Id.* at 306-308.) He also indicated that he did not know whether Plaintiff's complications were related to the catheterization procedure or the use of the CP stent:

> Q. Do you have any scientific evidence that the complication that [Plaintiff] had in this case, was related to the C-P stent as a device?
> A. I don't know.
> Q. Do you have any scientific evidence that the complication that [Plaintiff] developed in this case, [sic] was a result of using a catheterization versus using a surgical approach to completing the Fontan?
> A. I don't know. *I think that's unlikely*.

(*Id.* at 307-08 (emphasis added).)

B. Medical Negligence

The Catheterization Fontan differs from the Surgical Fontan in the procedure and the device used to achieve a Fontan physiology in the patient. Both the procedure and the device could form the basis for a medical negligence claim. In order for either to form the basis for a medical negligence claim that survives summary judgment, Plaintiff must produce expert testimony indicating that the use of the catheterization procedure, the CP stent, or some combination of the two, caused Plaintiff's injuries. *See* 18 Del. C. § 6853(e); *see also O'Donald*

v. McConnell, 858 A.2d 960, 960 (Del. 2004) (granting defendant's summary judgment motion because plaintiff had not satisfied the Health Care Act's expert testimony requirement); *Burkhart*, 602 A.2d at 59-60 (same); *Davis v. St. Francis Hosp.*, No. 06-045, 2002 Del. Super. LEXIS 272, at *6-8 (Del. Super. Ct. July 26, 2002). Plaintiff's expert must give an opinion that the defendant's deviation from the standard of care was the "but for" cause of the plaintiff's injury – the direct cause without which the harm would not have occurred. *See Davis*, 2002 Del. Super. LEXIS 272, at *7-8; *see also Culver v. Bennet*, 588 A.2d 1094, 1097 (Del. 1991).

The expert testimony requirement is not formalistic. Rather, it reflects the policy determination by the Delaware General Assembly that finders of fact must have the guidance of competent medical experts in order to navigate the complex, and often emotionally charged, issues in medical negligence cases. *See O'Donald*, 858 A.2d at 960 (noting that the Health Care Act's expert testimony requirement embodies the Delaware General Assembly's determination that "the proximate cause of injuries that are claimed to be attributable to medical negligence are not within the common knowledge of a layperson"). To that end, the Delaware Supreme Court has consistently held that the medical experts need not "couch their opinions in legal terms or . . . articulate the standard of care with a high degree of legal precision or with 'magic words.'" *Green v. Weiner*, 766 A.2d 492, 495 (Del. 1999); *Simmons v. Bayhealth Med. Ctr., Inc.*, 950 A.2d 659, 659 n.7 (Del. 2008) (*citing Green*); *Barriocanal v. Gibbs*, 697 A.2d 1169, 1172 (Del. 1997) (holding medical expert in informed consent case need not use "magic words" in his expert report); *see also McCusker v. Surgical Monitoring Assocs.*, No. 01-891, 2005 U.S. Dist. LEXIS 7298, at *19 (D. Del. Feb. 7, 2005) (*citing Green*); *Bonesmo v. Nemours Found.*, 253 F. Supp. 2d 801, 807 (D. Del. 2003) (same). In *Barriocanal*, the Delaware Supreme Court

admonished against "exalt[ing] form over substance" when reviewing medical expert reports. 697 A.2d at 1172. Thus, a report need not have words or phrases, such as "caused by" or "but for." By the same token, the fact that a plaintiff produces an expert report does not automatically mean that section 6853 is satisfied. The proper inquiry of a court reviewing a plaintiff's expert testimony is whether the expert has provided the finder of fact with guidance, reasonably based on the application of medical knowledge to the facts of the case, in determining that the defendant deviated from the standard of care and that the deviation resulted in the plaintiff's injury.

Although courts should focus on the substance of expert reports and should not read them myopically, scanning for legalese or buzz words, expert reports must nonetheless convey an opinion with reasonable clarity. "[W]here two possible causes may explain an injury, one of which can be said to be defendant's fault while the other is not, the plaintiff cannot recover without [medical expert testimony] demonstrating that the fault-based cause was more likely the source of the injury." *McCusker*, 2005 U.S. Dist. LEXIS 7298, at *11-12 (*citing Hammond v. Colt Ind. Operating Corp.*, 565 A.2d 558, 561 (Del. 1989)); *see also Bonesmo*, 253 F. Supp. 2d at 809 (holding that where treatment that could have decreased risk to patient was negligently withheld, plaintiff's medical expert had to address the question of whether "based on reasonable medical probabilities, the introduction of the treatment [the expert] recommend[ed] would have prevented the development" of the patient's life-threatening complication or prevented the patient's death).

In this case, neither Dr. Grossfeld's report nor his deposition testimony convey, explicitly or implicitly, his opinion that the use of the CP stent, the completion of Plaintiff's Fontan by

catheter, or some combination of the two was the "but for" cause of Plaintiff's PLE or plastic bronchitis. In fact, Dr. Grossfeld's report does not address the issue of causation and Dr. Grossfeld acknowledged at his deposition that he did not know whether the CP stent or catheterization caused Plaintiff's harm. (Grossfeld Dep. at 307-08.) There is considerable evidence in this record suggesting that Plaintiff's PLE and plastic bronchitis were potential outcomes of creating a Fontan physiology in Plaintiff's heart, regardless of how that physiology was achieved. Because an alternative explanation of Plaintiff's condition exists and because Dr. Grossfeld does not rule out that explanation as a cause or say that the Catheterization Fontan or CP stent made those conditions more likely, Plaintiff has not established the required causation. *See McCusker*, 2005 U.S. Dist. LEXIS 7298, at *11-12.

A review of the record reveals that Plaintiff's PLE and plastic bronchitis are known outcomes of the Fontan procedure that can occur absent the negligence of a physician. Plaintiff's medical expert conceded this at his deposition, when he testified as follows:

> Q: Would you agree with me that you can develop both plastic bronchitis and protein losing enteropathy absent medical practice or negligent care?
> A: Yes.
> Q: Would you agree with me that protein losing enteropathy and plastic bronchitis are both known what we call complications, quote, unquote, of the Fontan completion?
> A: Yes.
> Q: And would you agree that protein losing enteropathy and plastic bronchitis both occur without any negligence by a physician?
> A: Yes.

(Grossfeld Dep. at 307.) Defendants' medical experts support Dr. Grossfeld's concession. For example, defense expert Dr. Lee Benson testified that the complications Plaintiff experienced "clearly could have happened with the surgical Fontan because all of these things are well documented after a surgical Fontan." (Doc. No. 33, Ex. VV at 54-55 (hereinafter, "Benson

Dep.").) Dr. Norwood and Dr. Benson both testified unambiguously that they do not believe that the CP stent was the cause of Plaintiff's PLE or plastic bronchitis. (*See* Norwood Dep. at 75-76; Benson Dep. at 55.) Plaintiff's attorney asked Dr. Benson, "[e]ssentially you say there is no causal relationship between the plastic bronchitis and the completion of the Fontan using the CP stent; is that fair to say?" (Benson Dep. at 54.) Dr. Benson replied, "Correct." (*Id.*) He further testified that "[t]here is absolutely no reason to believe that [the Catheterization Fontan] would be any different than a surgical Fontan because it's exactly the same thing except you don't need open heart surgery to get it done." (*Id.* at 55-56.) Dr. Norwood gave similar testimony:

> I know of nothing chemically about the [CP] stent and its makeup that is different from the stuff that goes into other children, where there is and where there isn't plastic bronchitis or protein losing enteropathy. There is no scientific connection in my mind between a pathway built out of a covered stent versus a baffle that runs along the inside of the right atrium.

(Norwood Dep. at 76.) Defendants' expert, pediatric heart surgeon Dr. Jeffery Jacobs, explained the matter similarly, stating that "Fontan completion with surgery and Fontan completion with transcatheter technology both result in an identical physiology and that identical physiology is equally as likely to create any of the[] complications" generally associated with the Fontan procedure. (Jacobs Dep. at 74.)

Dr. Grossfeld does not disagree with these observations in his report or in his deposition testimony. Furthermore, Plaintiff's current physicians at CHOP view a Fontan take-down as a possible treatment for Plaintiff's plastic bronchitis, "since it appears that during [Plaintiff's] period of having Hemi-Fontan physiology she had no evidence of cast formation." (Doc. No. 33, Ex. SS at 2. *Cf.* J. Guinan Dep. at 294 (Plaintiff's mother discussing her understanding that a take-down Fontan is a "last resort kind of thing"); K. Guinan Dep. Vol. I at 199-200 (discussing

Dr. Rychik's reservations about performing a take-down Fontan).) The fact that the doctors at CHOP are considering a take-down Fontan because it would return Plaintiff to a Hemi-Fontan physiology, without considering a subsequent Surgical Completion of the Fontan, simply reinforces the testimony of all the doctors that Plaintiff's problems stem from her current cardiac physiology and not how that physiology was achieved. *See McCusker*, 2005 U.S. Dist. LEXIS 7298, at *11-12; *Bonesmo*, 253 F. Supp. 2d at 809.

Bonesmo is instructive in this regard. 253 F. Supp. 2d 801. In *Bonesmo*, the plaintiffs' decedent was a child born with hypoplastic left heart syndrome. The child was treated at the A.I. duPont Hospital by Dr. Norwood and Dr. Murphy, the Medical Defendants in this case. As part of her treatment, the child had a central venous catheter ("CVC") "inserted into her subclavian vein to administer various medications." *Id.* at 803. After the CVC was inserted, the child developed a thrombus that blocked blood flow to her brain, resulting in loss of neurological function and eventually death. *Id.* In the malpractice suit that followed, the plaintiffs offered expert testimony that deep vein thrombosis, a potential risk of the procedure absent negligence, caused their child's death. The court found insufficient expert testimony regarding causation, reasoning that:

> [A]lthough [plaintiffs' expert] states that the risk of deep vein thrombosis should have been decreased by the treatment she proposed, she is uncertain as to the degree. Moreover, she also notes that once deep vein thrombosis develops, the mortality rate among children is high. What is left to question is whether based on reasonable medical probabilities, the introduction of the treatment she recommends would have prevented the development of deep vein thrombosis, and, more importantly, once deep vein thrombosis developed, whether [the child's] death would have been prevented. As a result, there is a serious question whether [plaintiff's expert's] opinion adequately addresses proximate cause . . . .

Id. at 809-10. Thus, where certain outcomes are known risks of a procedure or course of

treatment – here, PLE and plastic bronchitis – and a plaintiff experiences those risks, that plaintiff's medical expert must explain how a course of treatment that comports with the standard of care – here, the Surgical Fontan – would have, based on "reasonable medical probabilities," prevented or significantly avoided those risks.

Dr. Grossfeld's does not provide this explanation. A fair reading of his report finds no opinion regarding the cause of Plaintiff's PLE or plastic bronchitis. For example, the report states, "[Plaintiff] has already had two additional procedures to fenestrate the [CP] stent – which was never meant to be fenestrated – in order to deal with her protein losing enteropathy and plastic bronchitis." (Grossfeld Report at 4.) There is no indication that the CP stent, the catheterization procedure, or the fenestration caused Plaintiff's PLE or plastic bronchitis. Moreover, Dr. Rome indicated that the fenestration was done because the doctors at CHOP simply "didn't identify other specific things to fix." (Rome Dep. at 22.)

Dr. Grossfeld's deposition testimony does not clarify his report. In fact, it provides a further basis for concluding that the report is devoid of an opinion regarding causation. When asked if Plaintiff's complications were related to the use of the CP stent or a result of the catheterization procedure, Dr. Grossfeld responded that he did not know. (*See* Grossfeld Dep. at 307-08.) Although Defendants' counsel framed the question as one of whether Dr. Grossfeld had "scientific evidence," the burden of establishing causation does not rest with Defendants. The fact that Dr. Grossfeld does not have "scientific evidence" did not prevent him from articulating his opinion "based on an analysis of the circumstances of the case." *McCusker*, 2005 U.S. Dist. LEXIS 7298, at *17 (*citing Green*, 706 A.2d at 496). When a novel procedure with a limited or no track record is at issue, a medical expert may still give an opinion based on

his expertise and review of the evidence. Such an informed opinion "is not merely speculation over the cause of a bad result." *Id.* If the expert can state his opinion with a reasonable degree of medical certainty or probability, then the plaintiff has met his burden. Dr. Grossfeld's testimony that Plaintiff's "future is truly unknown" is not sufficient. (Grossfeld Dep. at 4) A truly unknown future is not a legally cognizable injury. *See Laskowski v. Wallis*, 58 Del. 98, 101 (Del. 1964) ("'The law does not permit a recovery of damages which is merely speculative or conjectural. As a general rule, it refuses to allow a plaintiff damages relating to the future consequences of a tortious injury unless the proofs establish with reasonable probability the nature and extent of those consequences.'" (*quoting Henne v. Balick*, 51 Del. 369, 373 (Del. 1954))). *Cf. Deleski v. Raymark Indus., Inc.*, 819 F.2d 377, 380 (3d Cir. 1987) (noting that under "New Jersey law, neither enhanced risk of disease nor the fear and emotional distress attendant upon that risk is compensable without some present physical manifestation of illness or injury" and that under Pennsylvania law, the plaintiff could not "state a legally cognizable 'claim for negligent infliction of emotional distress based on the risk to her own health . . . unless and until she manifest[s] physical injury . . . .'") (alteration in original, citations omitted); *United States v. Anderson*, 669 A.2d 73, 74 (Del. 1995) (declining to answer certified question from the United States District Court for the District of Delaware as to whether increased risk resulting from medical malpractice was an independent cause of action).

Causation has always been an issue in this case. Defendants have raised it throughout the litigation, in their expert reports, during depositions, and in briefing. (*See, e.g.*, Benson Dep. at 54-55; Doc. No. 21 at 18-20.) Defendants questioned Plaintiff's parents repeatedly on the issue. (*See* J. Guinan Dep. at 153-54, 247-48, 313-13; K. Guinan Dep. Vol. I at 139-41, 293-97; K.

Guinan Dep. Vol. II at 63-64, 143.) Plaintiff's counsel described the "gist" of one of Defendants' expert reports as being "that transcatheter Fontan completion with covered stent is not the cause of any problems currently experienced by [Plaintiff] . . . ." (Jacobs Dep. at 34.) Defendants questioned Dr. Grossfeld about causation at his deposition. (Grossfeld Dep. at 307-08.) In preparing his report, Dr. Grossfeld relied on several documents in which causation was clearly raised as an issue, including the depositions of Plaintiff's parents, Dr. Norwood, and Dr. Cheatham. (*See* Grossfeld Report at 1-2.) Moreover, Delaware law, both as codified at section 6853 and as interpreted by the Delaware Supreme Court, is unequivocal with regard to Plaintiff's burden on the issue of causation. *See* 18 Del. C. § 6853(e); *Burkhart*, 602 A.2d at 59-60. A review of the record before us, with all inferences drawn in favor of Plaintiff, does not establish causation as required under Delaware law.[6] Accordingly, Defendants are entitled to summary judgment.

C. Informed Consent

The issue of the nature and extent of the information given to Plaintiff's parents before consenting to the Catheterization Fontan is the subject of significant dispute. The dispute

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[6] The fact that Plaintiff suffers from PLE and plastic bronchitis does not, standing alone, compel a different result. *See McCusker*, 2005 U.S. Dist. LEXIS 7298, at *10 ("Standing alone, an undesirable outcome, even an unusual one, is not a basis for relief."); *Duryea v. Perrotta*, No. 08-005, 1999 Del. Super. LEXIS 557, at *6 (Del. Super. Ct. Oct. 27 1999) ("Unusual or upsetting results alone are not sufficient evidence of malpractice or negligence."). Similarly, section 6853 precludes the application of *res ipsa loquitur*. *See Williams v. Dyer*, No. 11-010, 1992 Del. Super. LEXIS 381, at *3-4 (Del. Super. Ct. Aug. 12, 1992) (rejecting "outright" the applicability of the doctrine of *res ipsa loquitur* to medical malpractice claims that do not fall into one of the three enumerated exception of section 6853); *Lacy v. G.D. Searle & Co.*, 484 A.2d 527, 530 (Del. Super. Ct. 1984) ("[T]he last sentence of § 6853, which bars drawing an inference or presumption of negligence on the part of a health care provider based upon facts which do not satisfy § 6853, makes *res ipsa loquitur* no longer applicable to cases involving health care providers if the facts do not fall within § 6853.").

focuses on whether Plaintiff's father signed a Numed Consent Form prior to the Catheterization Fontan. It is not disputed that Plaintiff's parents signed the duPont Consent Form, which described in general detail the nature of the Catheterization Fontan. (*See* duPont Consent Form.) Plaintiff's parents were aware that the Surgical Fontan was a treatment option. (*See, e.g.*, J. Guinan Dep. at 76-77, 283-84.) Since Plaintiff's parents consented to the Catheterization Fontan, the Health Care Act governs the disposition of Plaintiff's informed consent claim and section 6853's expert testimony requirement applies to these claims. *See Valentine v. Mark*, No. 12-244, 2004 Del. Super. LEXIS 352, at *8 (Del. Super. Ct. Oct. 20, 2004) (applying the Health Care Act's requirements to an informed consent claim and holding that informed consent claims "cannot . . . be used as a backdoor around the requirement that causation in medical negligence cases be supported by expert testimony"); *Patten*, 1989 Del. Super. LEXIS 222, at *7-8. In *Brzoska*, the Delaware Supreme Court stated:

> [i]n the malpractice context, informed consent is statutorily defined and requires the patient to demonstrate the health care provider failed to supply information concerning the treatment or procedure "customarily given" by other "licensed health care providers with similar training and/or experience" in the community.
>
> In our view, the tort of battery is properly limited in the medical/dental setting to those circumstances in which a health care provider performs a procedure to which the patient has not consented. In other words, "a battery consists of a touching of a substantially different nature and character than that which the patient consented." A physician may be held liable for battery when he or she obtains the consent of the patient to perform one procedure and the physician instead performs a substantially different procedure for which consent was not obtained. A patient's consent is not vitiated, however, when the patient is touched in exactly the way he or she consented. If a health care provider violates his or her duty of care in obtaining the consent of the patient by failing to disclose all relevant information (risks) that a reasonable person would deem significant in making a decision to have the procedure, the action should be pleaded in negligence - not battery.

Brzoska, 668 A.2d at 1366.

Plaintiff's parents consented to the Catheterization Procedure. Therefore, their claim sounds in negligence and not battery. *See id.* Under *Brzoska*, the dispute over whether Plaintiff's parents signed the NuMed Consent Form is a dispute over the adequacy of the information conveyed. In other words, it is a dispute over whether the Medical Defendants satisfied their duty of care to Plaintiff to give her parents "information regarding such treatment, procedure or surgery to the extent customarily given to patients, or other persons authorized to give consent for patients by other licensed health care providers in the same or similar field of medicine as the defendant." 18 Del. C. § 6852(a)(2); *see also* 18 Del. C. § 6801(6) (defining informed consent as information "comprehensible to general lay understanding, of the nature of the proposed procedure or treatment and of the risks and alternatives to treatment or diagnosis which a reasonable patient would consider material to the decision whether or not to undergo the treatment or diagnosis"). It is not a dispute over whether the procedure performed is "a substantially different procedure for which consent was not obtained." *Brzoska*, 668 A.2d at 1366. Accordingly, whether Plaintiff's parents viewed or signed the Numed Consent Form is not determinative of the issue here. *Valentine* and *Patten* make it clear that the Health Care Act's expert testimony requirements apply to informed consent claims. Plaintiff has not satisfied her burden of producing medical expert testimony regarding causation. Accordingly, Defendants are entitled to summary judgment on this claim.

D. Fraud

Plaintiff predicates her fraud claim on the Medical Defendants' failure to disclose to Plaintiff's parents material facts concerning Plaintiff's treatment. (*See* Doc. No. 29 at 31-34.) Such a theory is precluded by Delaware law. The Health Care Act defines negligence as "any

tort or breach of contract based on health care or professional services rendered, or which should have been rendered, by a health care provider to a patient." 18 Del. C. § 6801(7). Fraud claims are tort claims and when, as here, they are "based on health care or professional services rendered, or which should have been rendered," they are incorporated into and superseded by section 6801(7). *See id.* It is not clear whether the definition of medical negligence in the Health Care Act means that Plaintiff cannot state a claim for fraud or merely that all fraud claims are turned into medical negligence claims subject to the Health Care Act. *Cf. Miller v. Spicer*, 822 F. Supp. 158, 171 (D. Del. 1993) (noting that "when the entirety of the [Health Care Act] is considered, claims for breach of implied contracts between patients and health care providers are prohibited"). In any event, Defendants are entitled to summary judgment on Plaintiff's fraud claim. Either the Health Care Act prohibits Plaintiff's fraud claim or the requirements of the Health Care Act apply and Plaintiff has failed to establish a genuine issue of material fact regarding causation.[7]

E. Medical Monitoring

Count VI of the Complaint alleges a medical monitoring cause of action premised on Plaintiff's claim that her future health is unknown as a result of the CP stent, which was not FDA approved when the Medical Defendants implanted it in her heart. In support of her claim, Plaintiff directs our attention to the events following the complaints by Plaintiff to the Hospital and the FDA. (*See* Doc. No. 30 at 16-17, 34-35, 43.)

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[7] The outcome would be same under New Jersey law, where fraud claims are subject to similar treatment. *See Howard*, 800 A.2d at 82 (holding that "we are not convinced that our common law should be extended to allow a novel fraud or deceit-based cause of action in this doctor-patient context that regularly would admit of the possibility of punitive damages").

On December 1, 2003, an FDA officer conducted an audit into the use of the CP stent at the Hospital. (March 30, 2004 Letter at 23.) The officer "charged the IRB with further investigation of Dr. Murphy's use of the CP stent." (*Id.*) In response to that charge, the Institutional Defendants conducted an investigation that resulted in the March 30, 2004 Letter to the FDA. The letter informed the FDA that the Medical Defendants had violated Hospital and IRB policies, had implanted an unapproved device in several patients, and had handled Plaintiff's parents' complaints poorly. (*See id.* at 1-2, 15-16.)

On April 16, 2004, the FDA sent Allen Tower a letter informing him that the FDA was concerned "that not all patients were properly advised that the CP stents were implanted without an approved Investigational Device Exemption (IDE) or an approved marketing application and that they are not receiving appropriate long-term medical follow-up." (Doc. No. 33, Ex. KK at 1 (hereinafter, "FDA Letter").) The FDA urged NuMed to consider conveying the following information and advice to the parents of patients who had received CP stents:

1. The NuMED CP stent was not approved for sale or investigational use by FDA in the United States at the time the patients were implanted with the devices.

2. The safety and effectiveness of the stent is not known at this time; therefore, patients should be advised to seek long-term medical follow-up.

3. Recommendations on the type of medical follow-up that should be completed and how frequently this follow-up should occur. These recommendations should indicate that the patients seek a qualified, unbiased physician with expertise in pediatric cardiovascular surgery, pediatric cardiology, adult cardiovascular surgery, or adult cardiology, depending on the needs of the patient.

4. Provide information in lay terms about the clinical symptoms that would help patients and their families recognize a developing problem and to seek appropriate medical care.

5. The identification of potential and known risks and complications associated with a failure of the CP stent . . . .

6. The name, address, toll-free telephone number, and hours of availability of a designated party at NuMED that patients or family members may contact in the event of questions or a request for additional information. The hours of availability should include some evening and weekend times.

7. All patients should be provided with a device identification card.

(*Id.* at 1-2.) On April 27, 2004, NuMed sent a letter to all implanting doctors and IRB chairpersons, including the Medical Defendants and Institutional Defendants. (Doc. No. 33, Ex. MM (hereinafter, "NuMed Letter").) The letter stated that "[t]he safety and effectiveness of the C.P. stent is unknown at this time; therefore NuMED is concerned that patients receive appropriate follow-up care." (*Id.* at 1.) It went on to suggest that patients who had CP stents implanted be evaluated on an annual basis "until full growth is reached" and that the evaluation include a history and physical exam, a chest x-ray, an echocardiogram, an EKG, and an MRI or spiral CT. (*Id.*) The letter also listed "[p]otential and known risks and complications with the C.P. Stent." (*Id.*)

Subsequently, the Institutional Defendants sent a letter to Plaintiff's parents informing them that a registry was being established to monitor patients who received the CP stent. (Doc. No. 23, Ex. E (hereinafter, "Nemours Letter").) The purpose of the registry was to allow the Institutional Defendants "to follow the status of [patients who had received the CP stent] in a systematic way, and to collect data on the device and to provide information to [the patient's] doctors to assist them in administering and devising the proper treatments for your child." (*Id.*)

Plaintiff contends that these letters, in conjunction with the testimony of Dr. Grossfeld that Plaintiff's future is truly unknown, are evidence that Plaintiff is entitled to medical

monitoring.

The Delaware Supreme Court has acknowledged medical monitoring but has never explicitly recognized medical monitoring as a legally cognizable cause of action. *See Mergenthaler*, 480 A.2d at 649 (affirming Delaware Superior Court's dismissal of plaintiffs' "claim for the expenses of medically required surveillance . . . where there [was] no present physical injury," which the court characterized as "direct contact" with asbestos).[8] When presented with an unsettled question of state law, a district court sitting in diversity must predict how the state's supreme court would resolve the issue, giving consideration to the decisions of intermediate state courts. *Franklin Prescriptions, Inc., v. N.Y. Times Co.*, 424 F.3d 336, 341 (3d Cir. 2005) (*citing Travelers Indem. Co. of Ill. v. DiBartolo*, 131 F.3d 343, 348 (3d Cir. 1997)); *Oglesby v. Penn Mut. Life Ins. Co.*, 889 F. Supp. 770, 773 (D. Del. 1995) (noting that where the Delaware Supreme Court had not addressed an issue, a federal district court sitting in diversity "must predict how the Supreme Court of Delaware would decide th[e] matter were it called upon to do so."); *see also Nationwide Mut. Ins. Co. v. Buffetta*, 230 F.3d 634, 637 (3d Cir. 2000)

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[8] Several lower courts in Delaware have given similar tacit acknowledgment of medical monitoring without expressly addressing its viability as a cause of action. *See, e.g.*, *Alderman v. Clean Earth, Inc.*, No. 04C-06-181, 2007 Del. Super. LEXIS 191, at *8 (Del. Super. Ct. June 26, 2007) (stating that "the court understands the point of medical monitoring" but that "[t]he problem . . . is that this is a property damage case); *Brzoska v. Olsen*, No. 92C-06-142, 1994 Del. Super. LEXIS 230, at *9 (Del. Super. Ct. May 2, 1994), *aff'd in part*, *rev'd on other grounds*, 668 A.2d 1355 (Del. 1994) (acknowledging plaintiffs claim for medical surveillance); *In re Asbestos Litig.*, No. 87C-09-24, 1994 Del. Super. LEXIS 685, at *5 (Del. Super. Ct. Aug. 5, 1994) ("Because the Court has determined that plaintiffs do not have a compensable physical injury, plaintiffs may not recover for the expenses of medical surveillance." (*citing Mergenthaler*, 480 A.2d at 651)); *McCracken v. Wilson Beverage*, No. 91A-10-004, 1992 Del. Super. LEXIS 394, at *5-8 (Del. Super. Ct. Oct. 15, 1992) *appeal dismissed*, No. 532, 1993 Del. LEXIS 191 (Del. May 3, 1993) (determining that a medical monitoring schedule was compensable under Delaware's Workers' Compensation statute, 19 Del. C. § 2322(a)).

(*quoting McKenna v. Ortho Pharm. Corp.*, 622 F.2d 657, 663 (3d Cir. 1980) ("In predicting how the highest court of the state would resolve the issue, we must consider 'relevant state precedents, analogous decisions, considered dicta, scholarly works, and any other reliable data tending convincingly to show how the highest court in the state would decide the issue at hand.'"). We predict that the Delaware Supreme Court would permit a claim for medical monitoring if it were confronted with the record currently before us.[9]

In *Mergenthaler*, the spouses of workers who allegedly had been exposed to asbestos fibers brought claims for mental anguish and medically required surveillance "as a result of the wives' contact with asbestos-fibers in the laundering of their husbands' work clothes." 480 A.2d at 649. To support their medical monitoring claims, the plaintiffs relied on the then-recent opinion of the New Jersey Supreme Court in *Ayers v. Twp. of Jackson*, 461 A.2d 184, 190 (N.J. 1984), one of the seminal medical monitoring decisions in the United States. *Mergenthaler*, 480 A.2d at 651. The Delaware Supreme Court found plaintiffs' reliance in *Ayers* "misplaced" because the plaintiffs in *Ayers* had come into direct contact with asbestos, whereas the *Mergenthaler* plaintiffs had established "no direct contact by the plaintiff-spouses with the asbestos, and no evidence was presented to show that they actually inhaled asbestos fibers." *Id.*

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[9] We note that federal courts have routinely predicted that state courts would adopt medical monitoring as a cause of action. *See, e.g.*, *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 852 (3d Cir. 1990) (Paoli I) (predicting that the Pennsylvania Supreme Court would recognize medical monitoring); *Friends for All Children, Inc., v. Lockheed Aircraft Corp.*, 746 F.2d 816, 824 (D.C. Cir. 1983) (Starr, J.) (predicting that the District of Columbia Court of Appeals would recognize a medical monitoring claim); *Abbatiello v. Monsanto Co.*, 522 F. Supp. 2d 524, 539 (S.D.N.Y. 2007) (New York); *Carey v. Kerr-McGee Chem. Corp.*, 999 F. Supp. 1109, 1119 (N.D. Ill. 1998) (Illinois); *Cook v. Rockwell Int'l Corp.*, 755 F. Supp. 1468, 1476 (D. Colo. 1991) (Colorado). *But see, e.g.*, *Norwood v. Raytheon Co.*, 414 F. Supp. 2d 659, 668 (W.D. Tex. 2006) (predicting that Texas courts would not recognize medical monitoring claim).

The court went on to determine that "based on this distinction, plaintiffs' [medical monitoring claim] contention fails." *Id.* The Delaware Supreme Court's decision to distinguish the plaintiffs' claims from those presented in *Ayers*, rather than to wholesale reject the medical monitoring cause of action, indicates that a different result would obtain if the evidence established direct contact with the hazardous material.

In this case, several considerations militate in favor of allowing Plaintiff to proceed with a medical monitoring claim. It is undisputed that Plaintiff has a Class III medical device in her body. *See* 21 U.S.C. § 360c(a)(1)(C) (defining Class III device as one "[used in] supporting or sustaining human life or . . . preventing impairment of human health, or [a device that] presents a potential unreasonable risk of illness or injury"). Moreover, it is undisputed that the device did not have premarket approval from the FDA at the time the Medical Defendants implanted it in Plaintiff and was thus considered an "adulterated" device. (*See, e.g.*, Doc. No. 33, Ex. UU (hereinafter, "Tower Plea Agreement" and "NuMed Plea Agreement").) Plaintiff had contact with the adulterated device. Indeed, it remains in her body. Thus, this is not a case like *Mergenthaler*, where recovery was denied because there was no direct contact. *See* 480 A.2d at 651. In addition, the FDA, NuMed, and the Institutional Defendants have all suggested that Plaintiff should receive follow-up care to monitor the CP stent. This is compelling, if not conclusive, evidence that medical monitoring is appropriate in this case. *See Friends for All Children*, 746 F.2d at 825 (treating defendant's experts' suggestion that plaintiffs receive diagnostic examinations as a persuasive rationale for recognizing a medical monitoring claim).

Although there exist countervailing policy considerations that militate against recognizing a medical monitoring tort, they are not compelling in the context of this case. *See,*

e.g., *Metro-North Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 443-44 (1997) (discussing potential for a "'flood' of less important cases" that could "entail systemic costs without corresponding benefits" if the Supreme Court were to recognize a "full-blown" medical monitoring tort in the context of the Federal Employers' Liability Act (FELA), 45 U.S.C. §§ 51 *et seq.*); *id.* at 443 (noting that "*extra* monitoring costs, over and above those otherwise recommended, . . . will sometimes pose special 'difficulties for judges and juries" (*quoting Conrail v. Gottshall*, 512 U.S. 532, 557 (1994)) (emphasis in original); *Friends for All Children*, 746 F.2d at 825 (identifying concern over potentially speculative nature of medical monitoring claims). *Contra In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 788 (3d Cir. 1994) (*Paoli II*) ("[T]he damages available in a medical monitoring claim – the cost of the tests – are not likely to be high enough to provoke a flood of litigation.").[10] In contrast, considerations of fairness, efficiency, and deterrence favor recognizing a cause of action for medical monitoring here.[11] *See*

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[10] Limiting the remedy to compensatory damages and expressly excluding non-economic and punitive damages serves as a disincentive to the hordes of plaintiffs' attorneys who the Supreme Court feared might be tempted to bring an onslaught of medical monitoring litigation. *See Paoli I*, 916 F.2d at 850 ("[A]n action for medical monitoring seeks to recover *only* the quantifiable costs of periodic medical examinations necessary to detect the onset of physical harm . . . .") (emphasis added); *Friends for All Children*, 746 F.2d at 826 (noting that "[i]n the absence of physical symptoms, emotional distress caused by potential risk may . . . be thought too speculative to support recovery").

[11] When the Supreme Court analyzed medical monitoring in the context of FELA, it categorized one body of medical monitoring case law as cases with "special recovery-permitting circumstances." *Buckley*, 521 U.S. at 440 (*citing Friends for All Children*, 746 F.2d at 824-25; *Hagerty v. L & L Marine Servs., Inc.*, 788 F.2d 351, modified, 746 F.2d 256 (5th Cir. 1986); *Simmons v. Pacor, Inc.*, 647 A.2d 232 (Pa. 1996)). Putting aside the issue of whether Delaware would recognize a medical monitoring cause of action generally, Plaintiff's case may well be a *sui generis* special recovery-permitting circumstance. The facts of this case – most importantly, Defendants' suggestion that Plaintiff seek out medical monitoring – impel us to permit Plaintiff to go forward with her claim for medical monitoring.

Friends for All Children, 746 F.2d at 825 (invoking "commonly shared intuitions of normative justice which underlie the common law of tort" and identifying medical monitoring as "a cost that is neither inconsequential nor of a kind the community generally accepts as part of the wear and tear of daily life"); *see also Buckley*, 521 U.S. at 443 ("[I]t is inequitable to place the economic burden of such care on the negligently exposed plaintiff rather than on the negligent defendant."); *Barnes v. Am. Tobacco Co.*, 161 F.3d 127, 139-40 (3d Cir. 1998) (*Barnes II*) (Scirica, J.) (*quoting Redland Soccer Club v. Dep't of the Army*, 696 A.2d 137 (Pa. 1997) (stating that "'allowing recovery for [medical monitoring] expenses avoids the potential injustice of forcing an economically disadvantaged person to pay for expensive diagnostic examinations necessitated by another's negligence,' and 'affords . . . victims, for whom other sorts of recovery may prove difficult, immediate compensation for medical monitoring needed as a result of exposure . . . .'")); *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 575 (6th Cir. 2005) (noting "that there is something to be said for disease prevention, as opposed to disease treatment. Waiting for a plaintiff to suffer physical injury before allowing any redress whatsoever is both overly harsh and economically inefficient"); *Paoli I*, 916 F.2d at 852 (recognizing deterrence function of medical monitoring tort).

F. Counts Three, Four, and Five of the Complaint

We have already dismissed Plaintiff's Assault and Battery Claim (Count III), Strict Liability Claim (Count IV), and Breach of Express and Implied Warranties Claim (Count V) against the Medical Defendants. (*See* February 14, 2007 Memorandum and Order.) The Institutional Defendants request that we do the same for them. (Doc. No. 24 at 14.) Plaintiff contests the Institutional Defendants' request (*see* Doc. No. 32 at 51-53), but her arguments are

not persuasive in light of our February 14, 2007 Memorandum and Order, which Plaintiff does not address in her briefing. *See generally ACLU v. Mukasey*, 534 F.3d 181, 187-89 (3d Cir. 2008) (*quoting Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988)) (discussing law of the case doctrine, which dictates that "'when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case'"). Accordingly, we will dismiss Counts Three, Four, and Five as to the Institutional Defendants for the reasons stated in the February 14, 2007 Memorandum and Order.

IV. CONCLUSION

For the foregoing reasons, Defendants' motions for summary judgment will be granted in part and denied in part.

An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MOLLY GUINAN	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 08-0228
A.I. DUPONT HOSPITAL FOR CHILDREN, et al.	:	

ORDER

AND NOW, this 6th day of February, 2009, upon consideration of the Motion of Defendant William I. Norwood, M.D., Ph.D., for Summary Judgment Pursuant to Rule 56 of the Federal Rules of Civil Procedure (Doc. No. 20), the Motion for Partial Summary Judgment to Dismiss the First Cause of Action (Doc. No. 21), the Motion for Partial Summary Judgment to Dismiss Count II of the Complaint Alleging Fraud and Intentional Misrepresentation and Punitive Damages Claim (Doc. No. 22), the Joint Motion of Defendants for Summary Judgment or Alternatively for Partial Summary Judgment on Medical Monitoring Claim Set Forth in Count VI (Doc. No. 23), and the Institutional Defendants' Motion for Partial Summary Judgment (Doc. No. 24), and all papers submitted in support thereof and in opposition thereto, it is ORDERED as follows:

1. Motion of Defendant William I. Norwood, M.D., Ph.D., for Summary Judgment is GRANTED;

2. The Motion for Partial Summary Judgment to Dismiss the First Cause of Action is GRANTED;

3. The Motion for Partial Summary Judgment to Dismiss Count II of the Complaint Alleging Fraud and Intentional Misrepresentation and Punitive Damages Claim is GRANTED;

4. The Joint Motion of Defendants for Summary Judgment or Alternatively for Partial Summary Judgment on Medical Monitoring Claim Set Forth in Count VI is DENIED;

5. The Institutional Defendants' Motion for Partial Summary Judgment is GRANTED.

IT IS SO ORDERED.

BY THE COURT:

R. Barclay Surrick, Judge